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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/152,698	09/02/1998	REGUPATHY MADIYALAKAN	AREX-P02-004	4505

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
05/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/152,698	MADIYALAKAN ET AL	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *30,71,76,85-88,96,99,100,103-114,117-119 and 123-134* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *85-88,96,117-119 and 134* is/are allowed.

6)☐ Claim(s) *30, 71, 76, 99, 100, 103-114, 123-129* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/28/07
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim 98 has been canceled. Claims 85, 88, 103, 106, 113 114 and 117 have been amended. Claims 129-134 have been added. Claims 30, 71, 76, 85-88, 96 and 99, 100, 103-114, 117-119 and 123-134 are pending and under consideration.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 129-132 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Newly added claims 129 and 131 specify that the antibody or antigen-binding fragment thereof comprises an Fc region which binds a Fcgamma receptor II. Claims 130 and 132 specify that the antibody is an IgG1 antibody. the originally filed disclosure does not support the instant limitations. It is noted that on page 26, the specification states "an Ab1 antibody, bound through its Fab region to a pre-determined antigen, may bind to the Fc receptor of a lymphocyte through the Fc region of the Ab1 antibody. This does not provide the written description of antibodies or fragments which comprise an Fc region which binds a Fcgamma receptor II. Further, the specification does not describe a limitation for the administered antibody to be of the IgG1 subtype. One of skill in the art would reasonable conclude that applicant was not in possession of the methods of claims 129-132 at the time the invention was filed.

The rejection of claims 30, 71, 76, 99, 103-110, 113, 114, and 123-128 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,241,985 is maintained for reasons of record. New claim 133 is also rejected for the same reasons of recordAlthough the conflicting claims are not identical, they are not patentably

distinct from each other because the scope of the claims of the '985 patent encompasses the instant claims. Claim 1 of the patent is drawn to "contacting" the CA125 antigen with the monoclonal antibody B43.13 and allowing the formation of a binding pair. The claim does not specify that the B43.13 antibody be administered directly to the host. The specification of '985 provides a preferred embodiment wherein a patients blood is removed and reacted with the B43.13 ex vivo and said modified blood re-administered to said patient (column 12, lines 56-62) which is within the scope of the instant claims requiring administration of the antigen-antibody complex as the re-administered blood would comprise the antibody antigen complex after contact with the antigen. The claims of the '985 patent require a cellular immune response, but the cytotoxic T cells generated by the method of the instant claims would inherently generate cytotoxic T cells because the interaction between B43.13 and the CA125 antigen produces a complex which elicits a host immune response against another epitope and inherently results in the generation of cytotoxic T-cells in the method of the patent. The claims of the patent do not specify that the antibody is a IgG type antibody, however, the B43.13 antibody is an IgG type antibody as evidenced by Madiyalakan et al (WO 99/65517).

The rejection of claims 30, 71, 76, 99, 103-110, 113, 114, and 123-128 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 276-282, 293-302, 313-322 and 333-338 of copending Application No. 09/376,604 is maintained for reasons of record. Claim 133 is rejected for the same reasons of record. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '604 anticipate the instant claims to the extent that they read on the CA125 antigen.

Independent claim 276 of the '604 application is drawn to "contacting" the CA125 antigen with an antibody that binds to a first epitope wherein an effective host T-cell response is elicited to CA125; independent claim 277 is drawn to "contacting" the CA125 antigen with an antibody that binds to an epitope and host immune response against a second epitope; independent claim 278 is drawn to "contacting" the CA125 antigen with an antibody that binds to a first epitope wherein an effective host T-cell response is elicited to CA125 and effective humoral immune response is generated to a second epitope. Claims 276-278 require the

formation of an immune complex, but do not specify that the immune complex is necessarily formed in vivo tot eh exclusion of ex vivo immune complex formation. The specification of '604 provides a preferred embodiment wherein a patients blood is removed and reacted with the binding agent ex vivo and said modified blood re-administered to said patient (page 41, lines 26-30) which is within the scope of the claims for the patent and anticipated the instant claims requiring administration of the antigen-antibody complex. The claims of the '604 application do not specify that the antibody is a IgG type antibody, however, claim 302 and 322 of '604 specify the B43.13 antibody, which is a IgG antibody as evidenced by Madilayakan et al (WO 99/65517).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn in light of applicants arguments.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.
5/13/2007

KAREN A. CANELLA PH.D
PRIMARY EXAMINER